



NOV - 5 2004

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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,446,194

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,446,194, which claims the human drug product COMTAN® (entacapone), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 416 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 416 days.

If the period of extension under 35 U.S.C. § 156 were calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 22, 2002 (67 Fed. Reg. 36008), the extension would be:

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,281 - 1,424) + 656 \\ &= 1,084 \text{ days}\end{aligned}$$

35 U.S.C. 156(c) provides for patent term extension for the regulatory review period after the issue date of the patent, subject to certain limitations. Since the regulatory review period began October 6, 1991, before the patent issue date (August 29, 1995), the period on or before the issue date (1,424 days) has been subtracted from the "testing phase" in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, however, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,084 days, would extend the patent from August 29, 2012 (35 U.S.C. § 154) to August 18, 2015, which is beyond the 14-year limit (the approval date is October 19, 1999, thus the 14-year limit is October 19, 2013). The period of extension is thus limited to October 19, 2013, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, August 29, 2012, to and including October 19, 2013, or 416 days.

The limitations of 35 U.S.C. § 156(g) do not operate to further limit the extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the

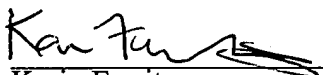
Official Gazette:

U.S. Patent No. : 5,446,194
Granted : August 29, 1995
Original Expiration Date : August 29, 2012
Applicant : Reojo J. Bäckström, et al.
Owner of Record : Orion-yhtymä Oy
Title : Pharmacologically Active Catechol Derivatives
Classification : 558/401
Product Trade Name : COMTAN® (entacapone)
Term Extended : 416 days
Expiration Date of Extension : October 19, 2013

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Mail Stop Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450
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Attn: Office of Patent Legal Administration

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.


Karin Ferriter
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RE: COMTAN®
FDA Docket No.: 00E-1344